FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

MYLAN DEFENDANTS' REPLY IN SUPPORT OF COMPANION MOTION TO EXCLUDE EXPERT TESTIMONY

Plaintiffs miss the point. The issue is not whether Mylan, as a wholesale distributor, may incur derivative liability if Actavis, the manufacturer of Digitek®, were to be found liable. The issue here is whether the opinions of Mark Kenny, the only Plaintiffs' expert as to Mylan, are admissible to support an independent cause of action against Mylan. Defendants argue that they are not.

Mr. Kenny's entire analysis and his conclusions concerning Mylan are contained in less than one page of his 50-page report. His reference to Mylan was added, as a litigation-driven afterthought[1], at the urging of Plaintiffs' Counsel and an undisclosed "co-expert," Salvatore Romano.[2] Mr. Kenny added these opinions to his report just days before Plaintiffs' expert

[1] Mr. Kenny testified that his role as an expert was to determine whether *Actavis*, as the manufacturer of Digitek®, complied with Good Manufacturing regulations and whether *Actavis* released adulterated products. His final report corroborates this testimony, as it contains no mention of Mylan in the "Introduction," "Work Plan," or "Expert Witness Final Summary" sections. Pla. Ex. 510 at 461:25-462:6; Pla. Ex. 511 at 5-7, 35.

[2] During his February 16, 2011 deposition, Mr. Kenny produced draft reports indicating that, as late as June 4, 2010, Salvatore J. Romano participated in the preparation of Mr. Kenny's report as a co-author and intended to testify at trial. Kenny Dep. Ex. 140 at 1-3, 5, attached as Exhibit 1; Kenny Dep. Ex.141 at 1-2, attached as Exhibit 2; *see also* Pla. Ex. 510 at 537:19-539:7, 540:14-20, 543:22-545:1, 547:20-548:5. Plaintiffs did not identify Mr. Romano in their June 15, 2010 liability expert disclosures. An early draft of the report, ultimately submitted on behalf of Mr. Kenny, contains a note from Mr. Romano directing Kenny to include the opinion that "Mylan was negligent in controlling its contractor Actavis." Ex. 2 at 16. This opinion was not included in a later draft reviewed by Plaintiffs' Counsel (Kenny Dep. Ex. 140) on June 4, 2010, but was added shortly thereafter at the

disclosures were due and only after meeting with Plaintiffs' Counsel and Mr. Romano to discuss an "advanced" draft of the joint report.[3]

Mr. Kenny proposes to testify that Mylan lacked adequate quality systems for qualifying and monitoring Actavis and that Mylan would have detected cGMP issues affecting Digitek® if it had conducted more frequent audits.[4] As discussed below, the Court should exclude Mr. Kenny's testimony because: (1) Mr. Kenny is not qualified to render opinions regarding the duties of wholesale distributors; (2) his opinions are litigation-driven; (3) his opinions are based on rank speculation; (4) they lack a reliable basis; and (5) his methodology is flawed.

KENNY'S OPINIONS AND METHODOLOGIES FAIL TO SATISFY THE REQUIREMENTS OF RULE 702 AND DAUBERT

The Mylan Defendants ("Mylan") incorporate by reference Part A of the "Law and Argument" section of the Memorandum in Support of Defendants' Motion to Exclude Plaintiffs' Liability Experts, Doc. 526, and all exhibits and authorities cited therein.

I. Kenny's Opinions About Mylan's Quality Control System Are Not Based On Sufficient Facts And Are Not The Product Of A Reliable Methodology

Mr. Kenny concludes that Mylan lacked adequate control systems for qualifying and monitoring Actavis, based on his review of "the records of over two hundred drug and device

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suggestion of Plaintiffs' Counsel. Pla. Ex. 510 at 479:11-14, 479:20-481:3; *see id*. at 484:1-24 (clarifying that Kenny Dep. Ex. 140 is an "advanced" draft).

[3] Messrs. Kenny and Romano met with Plaintiffs' Counsel in Newark, NJ on June 4, 2010 to discuss their semi-final draft report (Ex. 1). *See* Pla. Ex. 510 at 438:11-439:14 (discussing representation by Romano that report "was in good shape" and would be completed the following week). During that meeting, Plaintiffs' Counsel inquired as to why there was no mention of Mylan in the report. *Id*. at 479:11-481:3. Mr. Kenny testified that, as of June 4, 2010, he had not reviewed any Mylan documents. *Id*. He was not aware that Mylan was a defendant in the litigation and did not know what Mylan's legal role was. *Id*.

[4] Mr. Kenny concedes that FDA conducted twelve (12) "extensive" cGMP inspections of Actavis over a period of 182 days, between 1999 and 2008. *Id*. at 310:22-312:7. The fact that FDA continued to allow Actavis to manufacture Digitek® during this period is undisputed.

companies" and his own personal understanding of cGMP.[5] Pla. Ex. 511 at 33-34. However, Mr. Kenny's conclusion was admittedly reached without an accurate understanding of Mylan's relationship with Actavis or Mylan's legal status and its corresponding obligations under FDA regulations.

A. Kenny concedes that he has "no idea" what Mylan's role was with respect to Digitek®.

Mr. Kenny testified, some seven months after completing his expert report, that he had "no idea" what Mylan's role was with respect to the manufacture and distribution of Digitek®. Kenny Deposition at 333:7-334:6; *see id.* at 334:10-21, 335:1-12. He explained that his understanding of the relationship between Mylan and Actavis was something he would have inferred from statements "in memos and the like." *Id.* at 335:1-12. Though Mr. Kenny was aware of the existence of a 1999 Supply and Distribution Agreement for Digitek® ("1999 Agreement")[6], he admitted that he had not bothered to review that document because he was looking for a "quality agreement" and assumed—incorrectly—that the 1999 Agreement did not contain information about the parties' responsibilities for cGMP and regulatory compliance. Pla. Ex. 617 at VI, VII; Pla. Ex. 510 at 511:1-512:1. *Contra id.* at 339:7-25, 367:10-368:3.

When confronted with the 1999 Agreement during his deposition, Mr. Kenny conceded that it did, indeed, contain provisions concerning responsibilities for cGMP and regulatory

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[5] Mr. Kenny testified that his conclusions concerning Mylan's obligations under cGMP are based on his experience working for various Johnson & Johnson entities. *Id.* at 373:9-22, 374:13-18. But Mr. Kenny was unable to recall a single situation during his 30 years with Johnson & Johnson in which he exercised quality assurance oversight for a drug product that was both sponsored and manufactured by an outside company. *Id.* at 374:13-18; 376:1-379:20; 381:10-382:15.

[6] The 1999 Agreement is the operative agreement between Actavis and Mylan for the distribution of Digitek®. It defines the respective roles and responsibilities of the parties and assigns responsibility for cGMP, quality assurance and regulatory compliance to Actavis, which is consistent with Actavis' obligations, under applicable regulations, as the sponsor and manufacturer of Digitek®. Pla. Ex. 617 at II, VII.

compliance, including detailed procedures for handling product complaints.[7] *Id*. at 512:2-514:6**.** He also conceded that the 1999 Agreement assigned responsibility for Digitek® regulatory compliance and quality assurance to Actavis, which is consistent with Actavis' obligations under federal regulations as the sponsor (ANDA holder) and manufacturer of Digitek®. *Id*. at 512:2-7, 515:16-516:3, 516:4-15, 516:16-517:7.

B. Kenny does not even know if Mylan's legal status as a wholesale distributor is "important" to his opinions concerning Mylan's legal duties.

Not only does Mr. Kenny have no idea what Mylan's role was with respect to the manufacture and distribution of Digitek®, but also, he has no understanding of Mylan's regulatory status as a wholesale distributor or how that status informs Mylan's obligations under cGMP regulations. In fact, Mr. Kenny does not even know if Mylan's legal status and regulatory obligations would be "important or not" to his opinions. *Id*. at 501:7-11; *see also* 388:5-8 (admitting that he is not sure if the legal status of the parties involved is fundamental to his opinions).

Mr. Kenny testified, unequivocally, that he is not an expert in regulatory affairs or pharmaceutical distribution.[8] *Id*. at 329:25-330:12; Pla. Ex. 509 at 181:12-182:5. He was not aware that Mylan's status, under FDA regulations, was that of a wholesale distributor for Digitek® and an authorized distributor of record for Actavis. Pla. Ex. 510 at 499:15-501:11, 501:24-503:1. Had he been aware of this information, he would not have known what to make of it. *See Id*. at 499:15-501:11 (Testifying that he is not familiar with the term "authorized distributor of record," is not qualified to interpret that term and "[does not] know if it's important

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[7] Mr. Kenny had no criticism of the 1999 Agreement. Pla. Ex. 510 at 511:16-21.

[8] When questioned about his use, during his deposition, of the terms "ANDA" and "NDA," Mr. Kenny admitted that the distinction between the two types of drug applications were "beyond his area of expertise." *Id*. at 329:25-330:12. He also testified that he was not familiar with the regulatory categories for distributors—specifically the regulatory definitions for "authorized distributor of record." *Id*. at 499:15-501:6.

or not" to determining Mylan's duties); 501:24-503:1 (learning that Mylan was considered a "wholesale distributor" under 21 C.F.R. 203.3 does not help him to understand what Mylan's role was with respect to Digitek®). In short, Mr. Kenny doesn't know what Mr. Kenny doesn't know. And what he doesn't know renders his opinions inadmissible under *Daubert*, because he lacks the requisite expertise concerning the duties of a pharmaceutical wholesale distributor, such as Mylan.

C. The legal responsibility for complying with cGMP is fundamental to Kenny's opinions.

Mr. Kenny admits that the legal responsibility for complying with cGMP is fundamental to any opinion he offers in this litigation concerning Mylan. *Id.* at 345:6-8, 10. He testified that it is his belief that pharmaceutical distributors, like manufacturers, are responsible for ensuring compliance with "all aspects" of cGMP in the manufacture of finished pharmaceuticals. *See id.* at 388:11-389:2. Not surprisingly, Mr. Kenny was unable to cite a single regulation in support of this belief.[9]

Q. Are you aware of any regulation that places a responsibility for compliance with manufacturing GMPs on a wholesale distributor?
A. I'm not aware.

Id. at 503:2-5. Mr. Kenny was also unable to cite any regulation requiring wholesale distributors of finished products:

[9] Mr. Kenny's belief that cGMP regulations impose identical obligations for product quality and conformance on manufacturers and distributors is directly contradicted by the cGMP regulations themselves. Section 210.2 explicitly limits a party's compliance obligations to the *operations in which the party is engaged*. 21 CFR. §210.2 (2011). Part 211 of the cGMP applies to the manufacture of "drug products," defined by Section 210.3 as product in a "finished dosage form." 21 CFR. 211.1, 210.3 (2011). It is undisputed that Actavis manufactured Digitek® in finished dosage form pursuant to its own ANDA and that Mylan purchased and distributed Digitek® pursuant to the 1999 Agreement.

(1) to establish separate quality agreements with finished product manufacturers; *Id*. at 503:6-505:10 (conceding that the regulations say nothing about Quality Agreements)[10]

(2) to conduct audits or inspections of finished product manufacturers; *Id*. at 505:11-25

(3) to require certificates of analysis or certificates of conformance from finished product manufacturers; *See id*. at 506:1-6, 516:4-15

(4) to conduct periodic chemical analyses of finished products. *Id*. at 506:7-10, 16-17.

Despite the fact that the federal regulations do not impose a duty on wholesale distributors, such as Mylan, to establish a so-called "quality agreement" with or to conduct audits of a finished product manufacturer, they form the wobbly foundation for Mr. Kenny's opinion that Mylan's quality control system over outside manufacturers was lacking. *See* Pla. Ex. 511 at 33.

As a last resort, Mr. Kenny falls back on unspecified "business norms" to support his opinion that Mylan, as a distributor, was responsible for ensuring "all aspects" of cGMP compliance in the manufacture of Digitek®. *See* Pla. Ex. 510 at 387:25-389:2. Again, Mr. Kenny was unable to provide any objective, verifiable support for this standard, which he characterized as just his "informal understanding." *Id*. at 389:3-23.

16 Q. Is there any document whatsoever that
17 establishes "business norms"?
18 A. Absolutely nothing.

D. Kenny did not conduct any analysis of Mylan's quality control system.

Conspicuously absent from Mr. Kenny's report is any reference to Mylan's internal Quality Assurance policies and procedures for outsourced products (i.e., finished products purchased from outside manufacturers for distribution). Pla. Ex. 511 at 33-34, 41-42. In light of his stated reliance on the review of "the records of over two hundred drug and device

[10] Plaintiffs' cGMP and Quality Systems expert, David Bliesner, testified that quality agreements are not required by FDA regulations and that they only became an industry norm between 3 to 5 years ago, or in the 2006 to 2008 timeframe. *See* Pla. Ex. 508 at 238:20-239:11.

companies" in arriving at his conclusion that Mylan's quality control system was inadequate, failure to review Mylan's own records calls into question both the basis for Mr. Kenny's opinions and his flawed methodology, rendering any opinion on this subject unreliable and inadmissible.

E. Kenny is not aware of any FDA criticism of Mylan's involvement in the distribution of Digitek.

Finally, Mr. Kenny conceded that he is not aware of any FDA criticism of Mylan with respect to Digitek®, and neither is Mylan. Pla. Ex. 510 at 520:6-521:3. Specifically, he is not aware of any evidence indicating that FDA ever cited Mylan for violations of cGMP associated with the manufacture of Digitek®. *Id*. He is not aware of any FDA criticism of Mylan's Vendor Management policies, its handling of Digitek®-related product complaints, its distribution of Digitek®, or its handling of the Digitek® recall. *Id*.

II. Kenny's Conclusion that Mylan Would Have Discovered cGMP Issues Affecting Digitek Prior to FDA Is not Based on Any Discernible Methodology

Mr. Kenny's conclusion that Mylan, had it conducted more frequent audits, would have detected cGMP issues affecting Digitek® before the FDA amounts to nothing more than rank speculation and *ipse dixit* (i.e., just "because I say so"). Mr. Kenny sets forth no basis to support such a conclusion. Indeed, his report is devoid of citations on this issue and he does not rely on any objective medical or scientific literature to support his opinions as to Mylan. *See id.* at 510 at 460:14-16; Pla. Ex. 511 at 33-34.

Mr. Kenny does not explain how Mylan, as a wholesale distributor, could possibly have been in a better position than FDA to discover cGMP issues affecting Digitek®. He is unable to identify any law or regulation requiring or authorizing a pharmaceutical wholesale distributor to audit or inspect a manufacturer or supplier. Pla. Ex. 510 at 505:11-25. Mr. Kenny concedes that FDA, the U.S. governmental agency charged with interpreting and enforcing the cGMP

regulations[11], conducted twelve (12) "extensive" cGMP inspections of Actavis over a period of 182 days between 1999 and 2008. *Id*. at 310:22-312:7. The fact that FDA continued to allow Actavis to manufacture Digitek® during this period is undisputed. Finally, Mr. Kenny did not attempt to test his theory by conducting his own cGMP audit of Actavis' production records, policies and procedures between 1999 and 2008.

CONCLUSION

Mr. Kenny's opinions improperly attempt to impose legal duties on Mylan that do not exist under federal regulations governing pharmaceutical distributors. Mr. Kenny—by his own admission—is not qualified to render opinions about the duties of pharmaceutical wholesale distributors or the applicable federal regulations. But at the urging of Plaintiffs' attorneys and the undisclosed "ghost expert," Salvatore Romano, he proposes to do just that. Mr. Kenny's opinions are based on inaccurate information about Mylan's role in the distribution of Digitek®, and on unsupported assumptions regarding Mylan's legal duties under federal regulations. His conclusions are derived from his own subjective beliefs and are based on rank speculation—not reliable scientific methods and principles. Even assuming, *arguendo*, that Mr. Kenny's conclusions are admissible, they do not support an independent cause of action against Mylan under a separate theory of negligence because they do not reliably establish the existence of or breach of any legal duty and the corresponding causal connection to Plaintiffs' alleged harm—the three elements essential to any independent cause of action against Mylan. Simply stated, Mr. Kenny cannot create a legal duty that does not exist under the law.

Purported experts, such as Mr. Kenny, are precisely the type of witnesses over whom the Court should exercise its gatekeeper role to prohibit from testifying. His testimony would be

[11] Mr. Kenny agrees that the cGMP regulations are FDA's expertly drafted law. Pla. Ex. 510 at 311:25-312:7.

unfounded, misleading and unhelpful in advancing the litigation. For all of the reasons described above, the Mylan Defendants respectfully ask the Court to exclude the opinion testimony of Plaintiffs' liability expert, Mark Kenny.

Respectfully submitted,

GUTHRIE & THOMAS, PLLC

Rebecca A. Betts, LIAISON COUNSEL
500 Lee Street East, Suite 800
Charleston, West Virginia 25301
Tel: (304) 345-7250
Fax: (304) 345-9941
E-mail: rabetts@agmtlaw.com

Attorney for Defendants

SHOOK, HARDY & BACON LLP

By: /s/ Harvey L. Kaplan
Harvey L. Kaplan, CO-LEAD COUNSEL
Madeleine M. McDonough, CO-LEAD COUNSEL
2555 Grand Blvd.
Kansas City, Missouri 64108-2613
Tel: (816) 559-2214
Fax: (816) 421-5547
E-mail: hkaplan@shb.com
E-mail: mmcdonough@shb.com

Attorneys for Defendants Mylan Inc., Mylan Pharmaceuticals Inc., Mylan Bertek Pharmaceuticals Inc. and UDL Laboratories, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on September 7, 2011, a copy of the foregoing Mylan Defendants Reply in Support of Companion Motion to Exclude Expert Testimony was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

Respectfully submitted,

GUTHRIE & THOMAS, PLLC

Rebecca A. Betts, LIAISON COUNSEL
500 Lee Street East, Suite 800
Charleston, West Virginia 25301
Tel: (304) 345-7250
Fax: (304) 345-9941
E-mail: rabetts@agmtlaw.com

Attorney for Defendants

SHOOK, HARDY & BACON LLP

By: /s/ Harvey L. Kaplan
Harvey L. Kaplan, CO-LEAD COUNSEL
Madeleine M. McDonough, CO-LEAD COUNSEL
2555 Grand Blvd.
Kansas City, Missouri 64108-2613
Tel: (816) 559-2214
Fax: (816) 421-5547
E-mail: hkaplan@shb.com
E-mail: mmcdonough@shb.com

Attorneys for Defendants Mylan Inc., Mylan Pharmaceuticals Inc., Mylan Bertek Pharmaceuticals Inc. and UDL Laboratories, Inc.